

REMARKS

A response to the Office Action dated October 20, 2009 was due by January 20, 2010. A Petition for a One-Month Extension of Time and the associated fee are enclosed herewith. Accordingly, this Response is timely filed.

Reconsideration of this application, as amended, is respectfully requested. By this Amendment, replacement drawing sheets 1/8-8/8 are being submitted under cover of a separate letter to the Official Draftsperson, various informalities in the specification and abstract are being corrected, section headings are being added to the specification, and claims 1-9 are being amended and new claim 10 added to more particularly point out and distinctly claim the subject invention. The addition of "new matter" has been scrupulously avoided. Claims 1-10 remain in this application.

In the initial Office Action, the drawings were objected to because the original drawings were dark and the details difficult to distinguish. In response, replacement drawing sheets 1/8-8/8 are being submitted herewith under cover of a separate letter to the Official Draftsman. The new drawings are believed to be clear. Accordingly, the Examiner is requested to approve and enter the replacement drawing sheets and withdraw this objection.

The abstract and specification were objected to because of various informalities. Applicant has carefully reviewed and revised the abstract and specification to remedy these informalities. Accordingly, the Examiner is requested to reconsider and withdraw this objection.

As requested by the Examiner, section headings have been added to the specification.

Claims 4, 6 and 8, as previously presented, were objected to because of certain noted informalities. These informalities have been rectified.

Original claims 1-9 were rejected under 35 U.S.C. 112, second paragraph as allegedly indefinite because the Examiner considered these original claims to be generally narrative and replete with grammatical and idiomatic errors. The Examiner also noted that there was insufficient antecedent basis for the term "core" in claims 3, 4 and 8.

The claims have been carefully reviewed and revised to alleviate the noted objections. Accordingly, the Examiner is requested to reconsider and withdraw this rejection.

Original claims 1-9 were also rejected under 35 U.S.C. 101 as directed to non-statutory subject matter because these claims allegedly recited part of the human body in combination with the device. The claims have been revised to avoid inclusion of such non-statutory subject matter, and, accordingly, this rejection is now believed to be moot.

Original claims 1-9 were also rejected under 35 U.S.C. 103(a) as allegedly obvious over Marnay et al. (Published International Application WO 2001/01893). This rejection, to the extent that it may be deemed applicable to the claims as now presented, is respectfully, but most strenuously traversed for the following reasons.

Amended independent claim 1 is directed to an intervertebral disc prosthesis especially constructed to permit introduction of the prosthesis by a postero-lateral approach route. The prosthesis comprises an element mounted with an orientation and self-centering capability between a first insert and a second insert adapted to be disposed between vertebral plateaus of two successive vertebral bodies. The first insert has a planar section to be fixed on a lower vertebral plateau. The element has a lower planar surface for support, with a limited capacity for translational displacement on the first insert, and an upper surface with a generally hemispherical form. The second insert has a planar section to be fixed on an upper vertebral plateau and, opposite thereto, a concave surface for cooperating with the hemispherical surface of the element, thereby providing multi-directional articulation. Furthermore, the first and second inserts have a generally circular shape in the form of a disc with a diameter of about 30 mm and, when juxtaposed with the element between the first and second inserts, define a total height of about 11 to 15 mm to permit introduction of the prosthesis by the poster-lateral approach route.

No such combination of features is taught, disclosed or suggested by the applied prior art.

PCT document WO 01/011893 discloses a rectangular-shaped prosthesis that is fitted by an abdominal anterior route and which constitutes a fixed intermediate prosthesis.

In contrast, according to the present invention, the disc prosthesis is round and has a diameter which is less than 30 mm in order to be inserted by a posterior route, given that the nerve elements --dural sac, roots, and also vessels-- do not make it possible to fit a larger prosthesis at this location. The height of the prosthesis is limited to 11 to 15 mm so as to be able to be introduced by the postero-lateral approach route. The overall shape of the prosthesis, the geometry of the inserts and the limitations on diameter and height all contribute to the use of the present prosthesis according to a new posterior approach route.

The claimed shapes and sizes are therefore not merely a design expedient but rather are specifically adapted to facilitate introduction of the prosthesis by a new postero-lateral approach route.

The possibility of posterior opening of the lumbar canal to fit the prosthesis permits curettage of the associated compression elements, which can be curetted only by this posterior route: narrow canal, disc hernia, and osteophytes. Further, the use of the posterior route allows the plexus elements to be respected in order to not dissect the large vessels or the ureter, which may be injured by the anterior approach routes used in the prior art.

The applied reference seeks to reduce the minimum structural height of an intervertebral implant by employing an inter-nested arrangement of upper and lower parts. These parts are substantially rectangular in cross-section (column 3, lines 61-62) and this prior art prosthesis is intended to be introduced from front to rear (column 6, lines 43-45).

The prior art prosthesis is not intended for introduction by a postero-lateral approach route and is not constructed, with the appropriate shape and dimensions for such introduction. Further, there is no suggestion in this reference to configure or adapt the prosthesis for this purpose.

For all of the above reasons, claim 1, as now presented, is believed to patentably distinguish over the prior art. The dependent claims are allowable for the same reasons as independent claim 1 from which they all ultimately depend, as well as for their own limitations.

Accordingly, all of the claims in this application are believed to be in condition for allowance and such action is respectfully requested.

If it would advance the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below indicated telephone number.

Respectfully submitted,



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